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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
05/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,029	LAWRENCE, DAVID S.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8 and 94-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8 and 94-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

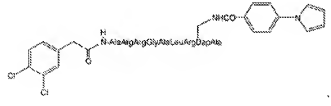
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/20/08,11/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Sequence non-compliance letter filed on March 04, 2009 is acknowledged. Claims 2-6, 9-93 have been cancelled and new claims 94-110 have been added in the response filed on October 17, 2008. Claims 1, 7-8 and 94-110 are pending in this application.

Restriction

1. Applicant's election without traverse of Group 1 (claims 1, 7-8) and the election of species  in the reply filed on October 17, 2008 is acknowledged. The restriction requirement is deemed proper and is made FINAL in this office action. Applicant indicates claims 1, 7, 8, 94-98, 109 and 110 read on the elected species. A search was conducted on the elected species, and this appears to be free of prior art. A search was extended to the other species, and these too appear to be free of prior art. Claims 1, 7-8, and 94-110 are examined on the merits in this office action.

TRADEMARK

2. The use of the trademark MICROBETA™ has been noted in this application at paragraphs [0172], [0176], [0177], [0202], [0203] of instant specification US 2007/0254312 A1. The use of the trademark MULTISCREEN™ has been noted in this

application at paragraphs [0191], [0192], [0193], [0194], [0208] of instant specification US 2007/0254312 A1. These should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Rejection

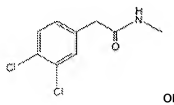
35 U.S.C. 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

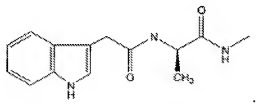
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 7-8, 94-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

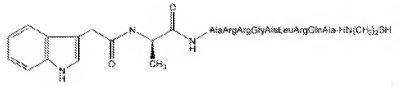
5. Claims 1, 7-8, 94-110 recite, "An inhibitor of a protein kinase Cα, the inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D (SEQ ID NO: 1), where A= AcHN-,

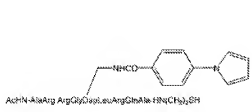
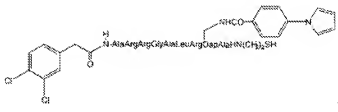


or



..." Dependent claims 8,



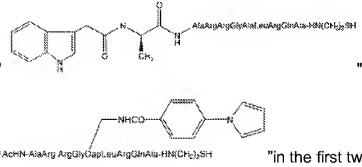
99-110 recite structures  ,  ,

for example. It is unclear if the HN- from the variable A is from the HN- of the amino acid alanine, or is an additional HN- component that would lead to a hydrazine bond to the HN- of the amino acid. For example, all amino acids have an amide component, (i.e., alanine has the structure ). Therefore, is unclear if HN- is part of the amino acid or separate from the HN- of the amino acid.

6. Claims 1, 7, 94-98 recite, "An inhibitor of a protein kinase Cα, the inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D (SEQ ID NO: 1)...X = any amino acid or amino acid mimetic...wherein any of the amino acid can alternatively be an analogous amino acid mimetic". It is unclear what modifications are encompassed within the term "analogous amino acid mimetic". The specification does not fully define is encompassed within the term "analogous amino acid mimetic" and "amino acid mimetic". The dictionary defines an analog as "a compound that resembles another in structure but is not necessarily an isomer" (see p. 4 of http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=derivative, enclosed), and "a compound that is structurally similar to another" (see p. 5 of http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=derivative,

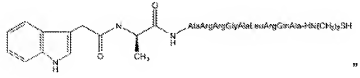
enclosed). Because claims 7, 94-98 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

7. Claim 8 recites the limitation



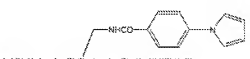
"in the first two lines of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 8 is dependent on claim 1 and claim 1 recites, "An inhibitor of a protein kinase Cα, the inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D (SEQ ID NO: 1)...where X = any amino acid or amino acid mimetic; B = Ala or DAP derivative...Hyd = Phe, Leu or Ile; C= Arg or Lys; and D = Ala or Dap derivative..." The amino acid glutamine in between Arg and Ala is not supported by SEQ ID NO: 1. The glutamine is at the position 8 of SEQ ID NO: 1. According to SEQ ID NO: 1, position 8 is variable "D" and this can be either Ala or Dap. Therefore, the limitation comprising amino acid glutamine lacks antecedent basis.

8. Claims 99-100 recite the limitation



" in the second line or the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 99 and 100 are dependent on claim 1 and claim 1 recites, "An inhibitor of a protein kinase Cα, the

inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D (SEQ ID NO: 1)...where X = any amino acid or amino acid mimetic; B = Ala or DAP derivative...Hyd = Phe, Leu or Ile; C= Arg or Lys; and D = Ala or Dap derivative..." The amino acid glutamine in between Arg and Ala is not supported by SEQ ID NO: 1. The glutamine is at the position 8 of SEQ ID NO: 1. According to SEQ ID NO: 1, position 8 is variable "D" and this can be either Ala or Dap. Therefore, the limitation comprising amino acid glutamine lacks antecedent basis.

9. Claims 101-102 recites the limitation " 

" in the second line or the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 101 and 102 are dependent on claim 1 and claim 1 recites, "An inhibitor of a protein kinase Cα, the inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D (SEQ ID NO: 1)...where X = any amino acid or amino acid mimetic; B = Ala or DAP derivative...Hyd = Phe, Leu or Ile; C= Arg or Lys; and D = Ala or Dap derivative..." The amino acid glutamine in between Arg and Ala is not supported by SEQ ID NO: 1. The glutamine is at the position 8 of SEQ ID NO: 1. According to SEQ ID NO: 1, position 8 is variable "D" and this can be either Ala or Dap. Therefore, the limitation comprising amino acid glutamine lacks antecedent basis.

35 U.S.C. 112, first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

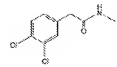
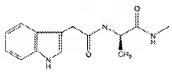
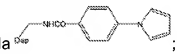
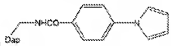
art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1, 7, 94-98 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for A-Ala-Arg-Arg-(any amino acid)-(Ala or Dap)-(Phe or Leu or Ile)-(Arg or Lys)-(Ala or Dap), does not reasonably provide enablement for the inhibitors wherein any of the amino acids are amino acid mimetics or analogous amino acid mimetics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature or the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (5) the breadth of the claims:

The claims are drawn to a An inhibitor of a PKCα, the inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D- (SEQ ID NO: 1), where A= AcHN-,  or  ; X= any amino acid or amino acid mimetic; B= Ala or a DAP derivative having the formula  ; Hyd= Phe, Leu or Ile; C= Arg or Lys; and D= Ala or Dap derivative having the formula  wherein any of the amino acids can alternatively be an analogous amino acid mimetic.

(2) The state of the prior art and (4) the predictability or unpredictability of the art::

With regards to the effect of amino acid substitution in a peptide or protein, the art is unpredictable.

Rudinger (Peptide Hormones, JA Parsons, Ed., 1976, 1-7) teaches that, "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted a priori but must be determined from case to case by painstaking experimental study" (see p. 6). Additionally, SIGMA states that with regards to design of peptide sequences that, "Even for relatively short sequences, there are essential and non-essential (or less important) amino acid residues, although the relative importance of the individual amino acid residues is not always easy to determine" (see p. 1). SIGMA further describes what effect some substitutions may

have, rather than what effect they will have on hydrophobicity, secondary structure (which will affect tertiary and quaternary structure), and solubility. Additionally, Schinzel et al (FEBS, 1991, 286(1, 2): 125-128) teach that the substitution of Lys^{539} by an arginine caused a 600 fold reduction, substitution of Arg^{534} by a glutamine caused an even larger 7000-fold reduction of the catalytic rate while substrate binding remained essentially unaffected. The reference teaches that Arg^{534} to Gln exchange reduces the catalytic rate near to inactivity and even the conservative Lys^{534} to Arg exchange caused marked decrease of activity (see abstract).

With regards to prediction of the native conformation of a protein (structure), the art is unpredictable. Berendsen (Science, 1998, 282: 642-643) states, "The prediction of the native conformation of a protein of known amino acid sequence is one of the great open questions in molecular biology and one of the most demanding challenges in the new field of bioinformatics" (see p. 642). Furthermore, Berendsen states that "Folding to the stable native state [computationally] has not (yet) occurred, and the simulations do not contain any relevant statistics on the process. The real protein will fold and refold hundreds to thousands of times until it stumbles into the stable conformation with the lowest free energy. Because this hasn't happened (and couldn't happen) in the simulations, we still cannot be sure of the full adequacy of the force field" (see p. 642).

Further, the effects of a single amino acid substitution can have substantial effects on proteins in structure and/or function and are exemplified by the difference between hemoglobin (Hb) and abnormal hemoglobins, such as sickle-cell hemoglobin (HbS). Voet et al teaches that the mutant hemoglobin HbE [GluB8(26)β to Lys] has, "no

clinical manifestations in either heterozygotes or homozygotes" (see p. 235). Further, Hb Boston and Hb Milwaukee both have single point mutations which results in altered binding affinity and ineffective transfer from the Fe(III) to Fe(II) oxidation state. Conversely, a single point mutation in Hb Yakima results in increased oxygen binding by the heme core, and in Hb Kansas, the mutation causes the heme center to remain in the T state upon binding oxygen (rather than structurally rearranging to the R state) (see p. 236). Further, HbS is a single point mutation, Val to GluA3(6)β (see p. 236), which results in deformation and rigidity of the red blood cell. The mutation also provides protection against most malarial strains.

Additionally, the art recognizes that "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted a priori but must be determined from case to case by painstaking experimental study". Additionally, SIGMA states that with regards to design of peptide sequences that, "Even for relatively short sequences, there are essential and non-essential (or less important) amino acid residues, although the relative importance of the individual amino acid residues is not always easy to determine" (see p. 1). SIGMA further describes what effect some substitutions may have, rather than what effect they will have on hydrophobicity, secondary structure (which will affect tertiary and quaternary structure), and solubility. Therefore, any modification on the polypeptide might have an affect on the polypeptide, thus vast numbers of experimentation would be required to see if the polypeptide modified with the amino acid mimetic or analogous amino acid mimetic would have the same affect in inhibiting PKCα as the wild type inhibitors. As with all peptides, activity is

based on the structure of the peptide. That is, the peptide has to have the proper structure to recognize the specific receptor for the peptide to be active. The state of the art for prediction of the native conformation of the protein is, at best, a vague science. For example, in peptide chemistry, Ngo et al teach that for protein and peptides, a "'Direct' approach to structure prediction, that of directly simulating the folding process, is not yet possible because contemporary hardware falls eight to nine orders of magnitude short of the task" (see p. 493). Accordingly, it is not known if an efficient algorithm for predicting the structure exists for a protein or peptide from its amino acid alone (see p. 492). Thus, activity of a given peptide cannot be based on its structure alone. Similarly, the Rudinger article (see the conclusion in particular) states "The significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from the case to case by painstaking experimental study." Finally, in an article published in Science, the author concluded that "one of the 'grand challenges' of high-performance computing-predicting the structure of proteins-acquires much of the flavor of the Holy Grail-quest of the legendary knights of King Arthur. It is extremely desirable to possess but extremely elusive to obtain" (see p. 643 in Berendsen). Berendsen et al states "at the present level of sophistication, [homology modeling] are effective for only 25% of the proteins for which the amino acid sequence is known" (see p. 642). It is known that proteins fold into their native conformation spontaneously and within seconds. The underlying principle of folding is known in the art yet the art lacks the ability to mimic native folding process (see p. 642 in Berendsen). "[E]xisting computers cannot sample enough configurations

in a reasonable time to come up with the thermodynamically stable native structure;...we are not too sure that the available force field descriptions, which we need to compute the energy of a each configuration, are accurate enough to come up with reliable free energy of a conformation" (see p. 642 in Berendsen). Berendsen et al discloses the principle of the "Levinthal's paradox" which states that if one was to assume that "three possible states for every flexible dihedral angle in the backbone of a 100 protein residue, the number of possible backbone configuration is 3^{200}. Even an incredibly fast computational or physical sample in 10^{-15}s would mean that complete sample would take 10^{80}s, which excides that age of the universe by more than 60 orders of magnitude." Other tools such as lattice models provide insight into principle of folding, but to provide no solutions to the real folding problems (see p. 643 in Berendsen). The art has recognized that even single point mutations can cause diverse effects on peptide activity. It has been shown in numerous peptides that a single amino acid can have deleterious effects on the peptide. For example, Bradley et al teach that a single substitution of Ala to Gly in six analogous structural peptides of an ankyrin protein resulted in dramatic and diverse effects on protein stability (see Bradley et al). Sickle cell anemia can be traced to a single point mutation at position six in the beta globulin protein. The instant application claims are open to amino acid mimetic modification at any position of any therapeutic polypeptides. The working examples given do not sufficiently establish whether any peptide encompassed by the claimed invention would behave similarly. Given that point mutations can lead to abolishment of activity, one would be burdened with undue experimentation to screen the numerous compounds in

attempting to find those that have the same activity as the wild-type therapeutic polypeptides.

Given that one could not determine the structure of a protein computationally, and that the effect of amino acid substitution is unpredictable, it flows logically that one would be unduly burdened with experimentation to determine the effect of amino acid substitution(s) in a peptide or protein, with regards to structure, function, or physical/chemical properties. Therefore, making any oligopeptide of instant SEQ ID NO: 1 where any of the amino acids can be an analogous amino acid mimetic that has the same activity as the claimed peptide, one would be unduly burdened with experimentation to determine the effect of amino acid content, substitution(s), addition and deletions in a peptide or protein, with regards to structure, function, or physical/chemical properties.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples:

The specification discloses inhibitors of PKCα having the sequences ARRGALRQA, ARRG-Dap-LRQA, ARRGALR-Dap-A, ARRG-Dap-R-Dap-A, ARRGALR-Dap-A (see paragraphs [0102]-[0105]). The specification discloses that the PKCα inhibitors comprise "consensus sequence of at least five amino acids or

mimetics, wherein at least one amino acid or mimetic is not essential to substrate binding, and wherein an amino acid or mimetic not subject to phosphorylation substitutes canonical Ser or Thr target residue in the consensus sequence; and a chemical moiety covalently bound to the compound at the at least one non-essential amino acid or mimetic in the consensus sequence..." (see paragraph [0081] of instant specification US 2007/0254312). The specification discloses that "an amino acid mimetic is an amino acid analog that can mimic the biological action of the amino acid. Preferred examples include D-amino acids) and other mimetics with non-hydrolyzable peptide bonds" (see paragraph [0097]). The specification discloses that "any one or more than one of the amino acid moieties can be a mimetic. Preferably, the mimetic moieties permit the peptide to retain its natural conformation, or stabilize a bioactive conformation" (see paragraph [0099]). The specification further discloses that "in preferred embodiments, the non-essential amino acid or mimetic and/or the amino acid or mimetic substituting a canonical Ser or Thr target residue is a diaminopropionic acid (Dap)" (see paragraph [0120]). The specification does not describe any other amino acid mimetic or analogous amino acid mimetic other than Dap. Description of a Dap is not sufficient to encompass numerous other amino acids, amino acid mimetics and other synthetic compounds that belong to the same genus. For example, SEQ ID NO: 1 has 8 amino acids. If any of the amino acids can be an analogous amino acid mimetics, there are vast numbers of different possibilities of inhibitor of PKCα. The specification however, does not provide for the myriad of oligopeptides embraced by the broad genus claimed. There is not sufficient amount of examples provided to encompass the

numerous characteristics of the whole genus claimed. Since there are vast numbers of compounds that can function as amino acid mimetic, the possibilities are limitless.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the reference above and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to make oligopeptides having skin-beneficial activities.

12. Claims 1, 7, 94-98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties,

functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

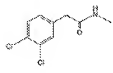
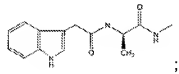
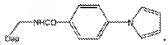
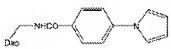
Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative

number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to a An inhibitor of a PKCα, the inhibitor comprising A-Ala-Arg-Arg-X-B-Hyd-C-D- (SEQ ID NO: 1), where A= AcHN-


, or 
; X= any amino acid or amino acid mimetic; B= Ala or a DAP derivative having the formula 
; Hyd= Phe, Leu or Ile; C= Arg or Lys; and D= Ala or Dap derivative having the formula 
wherein any of the amino acids can alternatively be an analogous amino acid mimetic. The generic statements amino acid mimetic and analogous amino acid mimetic do not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that can form cross-linking or can be cross-linked,

and make up the class of proteases. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as amino acid mimetics or analogous amino acid mimetics. The specification discloses inhibitors of PKCα having the sequences ARRGALRQA, ARRG-Dap-LRQA, ARRGALR-Dap-A, ARRG-Dap-R-Dap-A, ARRGALR-Dap-A (see paragraphs [0102]-[0105]). The specification discloses that the PKCα inhibitors comprise "consensus sequence of at least five amino acids or mimetics, wherein at least one amino acid or mimetic is not essential to substrate binding, and wherein an amino acid or mimetic not subject to phosphorylation substitutes canonical Ser or Thr target residue in the consensus sequence; and a chemical moiety covalently bound to the compound at the at least one non-essential amino acid or mimetic in the consensus sequence…" (see paragraph [0081] of instant specification US 2007/0254312). The specification discloses that "an amino acid mimetic is an amino acid analog that can

mimic the biological action of the amino acid. Preferred examples include D-amino acids) and other mimetics with non-hydrolyzable peptide bonds" (see paragraph [0097]). The specification discloses that "any one or more than one of the amino acid moieties can be a mimetic. Preferably, the mimetic moieties permit the peptide to retain its natural conformation, or stabilize a bioactive conformation" (see paragraph [0099]). The specification further discloses that "in preferred embodiments, the non-essential amino acid or mimetic and/or the amino acid or mimetic substituting a canonical Ser or Thr target residue is a diaminopropionic acid (Dap)" (see paragraph [0120]). The specification does not describe any other amino acid mimetic or analogous amino acid mimetic other than Dap. The working examples describe different PKCα inhibitors having "Dap" at positions 5, 8 and both 5 and 8. Description of a Dap is not sufficient to encompass numerous other amino acids, amino acid mimetics and other synthetic compounds that belong to the same genus. For example, SEQ ID NO: 1 has 8 amino acids. If any of the amino acids can be an analogous amino acid mimetics, there are vast numbers of different possibilities of inhibitor of PKCα. The specification however, does not provide for the myriad of oligopeptides embraced by the broad genus claimed. There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed. Since there are vast numbers of compounds that can function as amino acid mimetic, the possibilities are limitless. There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Julie Ha/
Examiner, Art Unit 1654